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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,023	02/17/2009	Elisabeth Woltering	BHC 031067	1717

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EXAMINER	
KIFLE, BRUCK	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
10/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,023	WOLTERING ET AL.	
	Examiner	Art Unit	
	Bruck Kifle	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,10,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/06, 10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 01/14/2004. It is noted, however, that applicant has not filed a certified copy of the 102004001871.5 application as required by 35 U.S.C. 119(b).

The filing date of this application is 02/17/2009. Applicants are hereby invited to make corrections according to MPEP 1800 (specifically 1810 and 1828) so that priority claims are accorded to the pending claims and avoid prior art rejections over intervening references.

Claim Rejections - 35 USC § 112

Claims 1-6, 9, 10, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) In claim 1 in the definition of group "A" it is stated "5- to 10-membered heteroaryl" and "A" is also defined as benzo fused groups. It is unclear what is intended as heteroaryl. Does the group "heteroaryl" in "A" include the latter four structures? A clarification of the heteroaryl group intended is required. The term "heteroaryl" is indefinite because it is not known how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present.

ii) The last line of the claims states "or a salt, solvate, or solvate of a salt thereof." Since Applicants intention is a pharmaceutical, insertion of the term is suggested, such as, "or a pharmaceutically acceptable salt thereof."

iii) Claims 4 and 5 are improperly presented. These claims are written as independent claims but rely on claim 1 for the definitions of the variables. Applicants need to rewrite these claims as either proper dependent claim (compound according to claim 1…) or as proper independent claims by including all of the limitations within the claims.

iv) Claim 6 is improperly multiple dependent. Appropriate correction is required.

v) Claim 6 has missing method steps. The last steps read "and then converted by methods known from the literature for the esterification or amidation of carboxylic acids into the compound of the formula (I) and the compound of the formula (I) is where appropriate separated into the stereochemically pure isomers and/or reacted with the appropriate (i) solvent and/or (ii) base or acid to give the solvate, salt and/or solvate of the salt thereof." Such language is inappropriate in a claim. Applicants need to set forth the conversion of the compound of formula (VI) into the compound of formula (I) in the claim.

vi) Regarding prevention in claim 12, it is unclear how one can say which humans and animals will for sure come down with disorders recited in order to prevent them. Deletion of prevention is suggested.

Claims 1-6, 9, 10, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical salt, does not reasonably provide enablement for solvates or solvates of the salts of the compound of formula I. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicants have not shown how one skilled in the art can arrive at a given solvate or solvate of a salt. None of the compounds made are crystallized

out as solvates or solvates of the salts. Arriving at a given solvate is not routine experimentation because it is unpredictable. One cannot make any solvate or hydrate of a compound.

Solvates are different chemical entities, they are not just impurities included in a compound. Pharmaceutically acceptable salts are additions and therefore not the same. Additions are obvious variation "after" the compounds are obtained, thus, can be allowed with the compounds. Solvates must be obtained at the time the invention was made. If Applicants do not have the solvates at the time the invention was made, they are not in possession of them because they are unpredictable.

All of the examples presented all failed to produce a solvate. The evidence of the specification is thus clear: These compounds do not possess the property of forming solvates; there is no evidence that such compounds even exist. Thus, this is a circumstance where the "specification is evidence of its own inadequacy" (In re Rainer, 377 F.2d 1006, 1012, 153 USPQ 802, 807). These cannot be simply willed into existence. As was stated in Morton International Inc. v. Cardinal Chemical Co., 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

Note that compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept under PCT Rule 13.1, 37 CFR 1.475(d). Claim 9 is not so linked as to form a single inventive concept. The compounds present in the pharmaceutical composition of claim 9 are of a different scope.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is 571-272-0668. The examiner can normally be reached on Mondays-Fridays from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruck Kifle/
Primary Examiner
Art Unit 1624

September 29, 2010